

### **REMARKS**

Applicants have now had an opportunity to carefully consider the Examiner's comments set forth in the Office Action of July 6, 2010.

Reconsideration of the Application is requested.

Claims 1, 3-4 and 6-17 are pending in the application.

### **REQUEST FOR INTERVIEW**

Applicants respectfully request the courtesy of a telephone interview with the Examiner and his supervisor. The purpose of the interview would be to discuss the references of record and the distinctions between the references and the inventive pending claims on the method and the bone substitute material produced by the method.

### **The Office Action**

Claims 1, 3-4, 6, 7 and 10-16 were rejected under 35 U.S.C. §103(a) as unpatentable over Kadoma, et al. (JP 11180705) in view of Breitscheidel, et al. (US Pub. No. 2004/0198909)

Claims 8, 9 and 17 were rejected under 35 U.S.C. §103(a) as unpatentable over Kadoma, et al. in view of Breitscheidel, et al. in view of Hall ("Experimental investigation on pore Size and Pore distribution," Bone Fracture and Regeneration, 1999, pp. 161-162).

For the reasons outlined below, it is submitted that the claims are in condition for allowance.

**Claim 1** recites a method of producing a bone substitute material in the form of a block predominantly composed of carbonate apatite for medical use. The method includes forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution. The calcium compound block contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight of the calcium compound block. The calcium compound block and/or the phosphate solution contains a carbonate group. The block of calcium compound is one which is prepared using an artificially synthesized calcium compound.

¶28 of Kadoma discloses a substance for use as adsorbents or carriers which

can be formed from gypsum dihydrate (calcium sulfate), which does not produce a carbonate apatite. The substance of Kadoma can also be formed from natural materials (limestone, shell, sea urchin shell and coral), which are first pulverized. Kadoma, ¶19-¶22. Thus, Kadoma teaches against using a block of calcium compound to form carbonate apatite.

The Examiner now acknowledges that Kadoma does not disclose that a calcium block is prepared using an artificially synthesized calcium compound. Breitscheidel is now cited as disclosing that limestone and synthetic calcium carbonate are “functionally equivalent.” Breitscheidel, however, is related to an entirely different art which has no relation to bone substitute materials. Specifically, Breitscheidel suggests the use of calcium carbonate as a filler material for plastics (see ¶53). There would have been no expectation that the finely divided filler materials of Breitscheidel, which are dispersed in a plastic matrix to influence strength and hardness of the plastic (¶52), would be functionally equivalent for forming a bone substitute material.

Nor is there any suggestion that these materials would be functionally equivalent when in a block. While the size of the filler particles is not mentioned in Breitscheidel, it is common for fillers in plastics to be finely divided, i.e., very different from a block, as presently claimed. There would be no expectation that the finely divided filler materials in Breitscheidel would be functionally equivalent to the block of calcium compound prepared using an artificially synthesized calcium compound presently claimed.

Further, the mere mention of fillers in the same sentence in Breitscheidel in would not have suggested that they are “functionally equivalent.” Also listed in the same sentence in Breitscheidel are carbon black, dolomite, silicates, silica, sand, diatomaceous earth, and aluminum silicates, such as kaolin, mica, and feldspar. One of ordinary skill in the art would not expect, from Breitscheidel, that carbon black is functionally equivalent to calcium carbonate for forming bone substitute materials, and therefore, there is no reason to expect that other materials drawn from this list are also functionally equivalent.

Moreover, Breitscheidel makes no suggestion that an artificially synthesized calcium compound block should be formed of the finely divided materials suggested as fillers or that even if it were, would contain substantially no powders such that powders

with a diameter of 20 micrometers or smaller are less than 1.0% by weight. No descriptions are found even suggesting that the materials in Breitscheidel would be functionally equivalent when in a block.

Accordingly, there would have been no reason for one of ordinary skill in the art to combine Breitscheidel with Kadoma. Further, even if such a combination were to have been made, the combination would not have suggested a block of calcium compound prepared using an artificially synthesized calcium compound which contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight.

Dependent claim 3 further recites that the calcium compound block is a foamed calcium compound. The Examiner draws attention to the "porous" apatite mentioned in claim 1 of Kadoma, and argues that this is a "foam" block. However, this is referring to the product, not to a block used in forming carbonate apatite by contacting the block with a phosphate-containing solution. The suggestion that the product is porous does not require the solid compound which is used as Kadoma's starting material to be porous, or even to be a foam block. Accordingly, claim 3 further distinguishes over Kadoma in view of Breitscheidel.

Dependent claim 12 adds that the phosphate solution contains a carbonate group. The phosphate solution of Kadoma does not contain a carbonate group. As previously noted, there is no suggestion to Kadoma's solution containing carbonate in ¶[0015]. ¶[0016] of Kadoma does mention a "calcium carbonate system," but this is in reference to the limestone and shell starting materials, rather than to the solution. Accordingly, claim 12 further distinguishes over Kadoma in view of Breitscheidel.

Dependent claims 13 and 16 recite that the phosphate solution contains ammonium carbonate. The Examiner argues that a phosphate solution containing ammonium carbonate is a matter of obvious design choice. However, there is no suggestion in any of the references as to the use of ammonium carbonate in a phosphate solution. Nor as the Examiner explained why it would have been obvious to select ammonium carbonate. The Examiner cites *In re Leshin*, 125 USPQ 416. In *Leshin*, the selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious. In the present case, however, the

Examiner has failed to show that ammonium carbonate in a phosphate solution was previously known for forming bone substitute materials. The Examiner has therefore failed to make a *prima facie* case for obviousness. Accordingly, claims 13 and 16 further distinguish over Kadoma in view of Breitscheidel.

Dependent claim 8 recites that the porous block has an average pore diameter in a range of 50-1000 $\mu$ m. The Examiner argues the Hall reference discloses this range. However, Hall relates to pore size for bone implants made of metal alloy. There is no suggestion that such a pore size is suited to forming a bone substitute material in the form of a block predominantly composed of carbonate apatite. Nor does Hall teach one of ordinary skill how to achieve this using Kadoma's calcium sulfate or even Breitscheidel's finely divided filler materials. Accordingly, claim 8 distinguishes over Kadoma in view of Breitscheidel and further in view of Hall.

Accordingly, it is submitted that claim 1 and claims 3, 7-8, and 10-6 dependent therefrom distinguish over the references of record.

**Claim 4** recites a bone substitute material produced by a method comprising forming carbonate apatite by contacting a block of calcium compound with a phosphate-containing solution, wherein the calcium compound block contains substantially no powders such that powders with a diameter of 20 micrometers or smaller are less than 1.0% by weight, and wherein the block of calcium compound is one prepared using an artificially synthesized calcium compound.

The material produced by Kadoma's method is very different to that claimed. The substance produced with natural calcium carbonate materials is formed from a powder by pulverization of these materials and would inherently have contaminants will result in a material which would cause inflammation due to histotoxicity.

Breitscheidel does not supply the deficiencies of Kadoma since Breitscheidel, like Kadoma, uses finely divided materials, but in this case, as a filler for plastic.

Moreover, one of ordinary skill in the art would not have considered the plastic-appropriate fillers of Breitscheidel as functionally equivalent for forming Kadoma's inorganic substance.

Dependent claim 6 recites that the artificially synthesized calcium compound is a foamed calcium compound. Neither Kadoma nor Breitscheidel suggests carbonate

apatite formed from a foamed, artificially synthesized calcium compound. Rather, both use finely divided materials.

Accordingly, it is submitted that claim 4 and claim 6 dependent therefrom distinguish over Kadoma in view of Breitscheidel.

**Claim 9** recites a method of producing a bone substitute material predominantly composed of carbonate apatite, which includes providing a porous body formed of a calcium compound. The body contains substantially no powders and has an average pore diameter in a range of 50-1000 $\mu$ m. The porous body is contacted with a phosphate-containing solution. The porous body and/or phosphate solution contains a carbonate group.

As noted above, there would have been no reason to combine Breitscheidel with Kadoma, as asserted by the Examiner. In particular, one of ordinary skill in the art would have no expectation of functional equivalency of an artificially synthesized calcium compound based on the filler materials of Breitscheidel proposed for use in plastics.

The Examiner argues that Kadoma, et al. with Breitscheidel, et al. discloses the claimed invention except for the pore size being between 500 and 1000 micrometers and cites Hall for this feature. The Hall reference discloses a pore size for bone implants made of metal alloy. However, Hall does not teach one of ordinary skill how to achieve such pore sizes using, for example, Kadoma's hydrated hardened body of gypsum fibrosum or even Breitscheidel's finely divided filler materials. Nor is there any suggestion that such a pore size would be appropriate to the non-metallic substance of Kadoma.

Accordingly, it is submitted that claim 9 and dependent claim 17 distinguish over the references of record.

**CONCLUSION**

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 1, 3-4, and 6-17) are now in condition for allowance.

☒ Remaining Claims, as delineated below:

(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT LESS HIGHEST NUMBER PREVIOUSLY PAID FOR		(3) NUMBER EXTRA
TOTAL CLAIMS	15	- 20 =	0
INDEPENDENT CLAIMS	3	- 3 =	0

☒ This is an authorization under 37 CFR 1.136(a)(3) to treat any concurrent or future reply, requiring a petition for extension of time, as incorporating a petition for the appropriate extension of time.


☒ The Commissioner is hereby authorized to charge any filing or prosecution fees which may be required, under 37 CFR 1.16, 1.17, and 1.21 (but not 1.18), or to credit any overpayment, to Deposit Account Number 06-0308.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is hereby authorized to telephone the undersigned, at 216.363.9000.

Respectfully submitted,

Fay Sharpe LLP

September 30, 2010  
Date

  
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Ann M. Skerry, Reg. No. 45,655  
Jay F. Moldovanyi, Reg. No. 29,678  
The Halle Building, 5th Floor  
1228 Euclid Avenue  
Cleveland, Ohio 44115-1843  
216.363.9000